MAY 22 2003 K030835

510 (k) Summary

Submitter's Name/Address:
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Date of Preparation of this Summary: March 12, 2003

Device Trade or Proprietary Name: 'Rapid One'-Propoxyphene Test

Device Common/Usual Name or Classification Name: Propoxyphene Test System

Classification Number/Class: [no classification regulation]/Class II

This 510(k) Summary is being submitted in accordance with the requirement of 21 CFR 807.92.

The assigned 510(k) number is: K030835

Predicate Device: MedTox Diagnostics, Inc. 2-Panel Propoxyphene/MAMP-MDMA Test. (510 (k) No. K002141).

Test Description:

The assay employed in the 'Rapid One'-Propoxyphene Test is based on the same principle of highly specific reactions between antigens and antibodies.

This assay is a one-step, competitive, immunoassay for the detection of propoxyphene and its metabolite norpropoxyphene in human urine. The test device consists of a membrane strip onto which a drug conjugate has been immobilized and a colloidal gold-multi-antibody complex is dried at one end of the membrane. In the absence of any drug in the urine sample, the colloidal gold-antibody complex moves with the urine by capillary action to contact the immobilized drug conjugates. Antibody-antigen reactions occur forming visible lines in the 'test' area.

When drug is present in the urine sample, the drug or metabolite will compete with its corresponding drug conjugate in the test area for the limited antibody sites on the colloidal gold-labeled antibody complex. If sufficient amount of drug is present, it will fill all of the available antibody binding sites, thus preventing attachment of the labeled antibody to the drug conjugate. An absence of a color band (line) in the 'test' area is indicative of a positive result.

A control band (line), comprised of a different antibody/antigen reaction, is present on the membrane strip. The control line is not influenced by the presence or absence of drug in the urine, and therefore, should be present on all reactions.

A negative urine will produce two colored bands, and a positive sample will produce only one band.

Intended use:

'Rapid One'-Propoxyphene Test is used for the qualitative detection of propoxyphene and norpropoxyphene in human urine. This immunoassay is a simplified screening method that provides only a preliminary result for use in determining the need for additional or confirmatory testing, i.e. gas chromatography/mass spectrometry (GC/MS.)

Performance Characteristics:

'Rapid One'-Propoxyphene Test will detect propoxyphene or norpropoxyphene at 300 ng/ml.

Reproducibility was evaluated using control urines containing concentrations above and below the stated cut-off. Negative controls were also used. All concentrations were verified by GC/MS. Each sample was tested four times, twice daily, for five days. The results confirmed the reproducibility of the 'Rapid One'-Propoxyphene Test performance.

Conclusion:

'Rapid One'-Propoxyphene Test is substantially equivalent to the previously cleared propoxyphene section of MedTox 2 Panel PPX/MAMP-MDMA Test (510(k) No. K002141).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Dr. Henry Wells
Vice President Product Development
American Bio Medica Corporation
9110 Red Branch Road
Suite B
Columbia, Maryland 21045

MAY 22 2003

Re: k030835
Trade/Device Name: Rapid One – Propoxyphene Test
Regulation Number: 21 CFR § 862.3700
Regulation Name: Propoxyphene Test System
Regulatory Class: II
Product Code: JXN
Dated: March 14, 2003
Received: March 17, 2003

Dear Dr. Wells:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K030835

Device Name:_____

Indications For Use:

'Rapid One'-Propoxyphene Test

'Rapid One'-Propoxyphene Test is a one-step lateral flow immunoassay for the qualitative detection of 300 ng/ml of propoxyphene and norpropoxyphene in human urine.

'Rapid One'-Propoxyphene Test is intended for professional use. It is not intended for over-the-counter sales to nonprofessionals. The assay is easy to perform, but should not be used without proper supervision. This immunoassay is a simplified, qualitative screening method that provides only a preliminary result for use in determining the need for additional or confirmatory testing, i.e. gas chromatography/mass spectrometry (GC/MS.)

'Rapid One'-Propoxyphene Test provides only a preliminary analytical result. A more specific alternate chemical method must be used in order to obtain a more confirmed result. GC/MS is the preferred confirmatory method. Clinical and professional judgment should be applied to any drug of abuse test result. Particularly when preliminary results are used.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

Prescription Use ✓ 510(k) K030835 OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)